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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GEOFFREY C. GURTNER, JAYAKUMAR RAJADAS, MICHAEL GABRIEL GALVEZ, and EVGENIOS NEOFYTOU[1]

Appeal 2017-000716
Application 12/577,006
Technology Center 1600

Before ULRIKE W. JENKS, ROBERT A. POLLOCK, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from the final rejection of claims 1, 7–10, 16, 18–20, and 22, 23, and 26–29. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

Appellants' invention relates to the treatment of chronic wounds by transdermal delivery of an agent that increases HIF-1α activity in the wound. Spec. ¶ 12. Such HIF-1α potentiating agents include deferoxamine, deferiprone, and deferasirox. *Id.*

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[1] Appellants identify the real party-in-interest as Leland Stanford Junior University. App. Br. 1.

Claims 1, 22, and 23 are independent. Claim 1 is illustrative (paragraphing added):

> 1. A method of treating a chronic skin wound on an individual, the method comprising:
>
> contacting said wound topically with a transdermal patch comprising an effective dose of deferoxamine embedded in a biodegradable polymer film comprising a non-ionic surfactant,
>
> wherein the transdermal patch comprises an adhesive; and an impermeable backing membrane;
>
> and wherein an effective dose of the deferoxamine transdermally penetrates the wound.

STATEMENT OF THE REJECTION

Claims 1, 7–10, 16, 18–20, 22, 23, and 26–29 stand rejected on the ground of nonstatutory double patenting over claims 34, 45–47, 49–51, 53, 69, and 71–73 of Application No. 11/136,254 (now U.S. Patent No. 8,829,051).

Claims 1, 7–10, 16, 18–20, 22, 23, and 26–29 stand provisionally rejected on the ground of nonstatutory double patenting over claims 1, 5, and 24–28 of copending Application No. 11/297,808.

Claims 1, 7–10, 16, 18–20, 22, 23, and 26–29 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Gurtner '189[2] or Gurtner

[2] Gurtner and Brownlee, US 2006/0100189 Al, published May 11, 2006.

'748,[3] (collectively, "Gurtner")[4] in view of Roreger,[5] Feng,[6] Mason,[7] and Lipp.[8]

DOUBLE PATENTING REJECTIONS

Appellants do not argue the merits of the double patenting rejections. App. Br. 2. In the absence of substantive arguments, we summarily affirm the rejections.

REJECTION UNDER 35 U.S.C. § 103(a)

We have reviewed Appellants' contentions that the Examiner erred in rejecting claims 1, 7–10, 16, 18–20, 22, 23, and 26–29 as unpatentable over the cited art. App. Br. 2–9. We disagree with Appellants' contentions and adopt the findings of fact and reasoning set forth in the Examiner's Answer and the Final Rejection dated January 9, 2015, ("Fin. Rej."). For emphasis, we highlight and address the following:

Findings of Fact

FF1. Gurtner is directed to treating or preventing the effects of hyperglycemia (e.g., promoting the healing of diabetic foot ulcers) by administering an ROS inhibitor, preferably deferoxamine. *See, e.g.*, Gurtner Abstract, ¶¶ 16, 19–20, 143, claims 1, 9–11, 25. Gurtner teaches

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[3] Gurtner and Brownlee, US 2006/0281748 Al, published Dec. 14, 2006.
[4] Gurtner '748 represents a continuation of Application No. 11/136,254, which published as Gurtner '189. Gurtner '748 and Gurtner '189, thus, share substantially the same Specification and need not be considered separately. For convenience, we cite herein to Gurtner '189.
[5] Roreger, US 6,117,437, issued Sept. 12, 2000.
[6] Feng et al., US 2007/0104769 Al, published May 10, 2007.
[7] Mason, US 2003/0082225 Al, published May 1, 2003.
[8] Lipp et al., US 5,676,968, issued Oct. 14, 1997.

that the ROS inhibitor may be administered transdermally (*id.* at ¶ 74, claims 32 and 49) and with pharmaceutically acceptable carriers and excipients (*id.* at ¶ 74, claims 33 and 50). The Examiner reasonably finds that deferoxamine would transdermally penetrate a wound because Gurtner "teaches transdermal application to the wound including diabetic foot ulcers." Fin. Rej. 8.

FF2. Roreger teaches a pharmaceutical formulation for delivery of an active agent to a wound comprising a coherent flexible gel sheet with the active agent homogenously distributed therein. *See* Roreger Abstract. The formulation may: contain PVP and ethyl cellulose (*id.* at 5:60–6:18); be designed to break down in the wound, i.e., may be biodegradable (*id.* at 5:9–43, 60–63); and may include ancillary substances including nonionic emulsifiers (*id.* at 6:19–41).

FF3. Feng teaches a bioabsorbable, water-soluble hemostatic cellulose-based wound dressing, which may include one or more nonionic surfactants in the range from about 0.1 % to about 5% by weight, and pharmaceutically active therapeutic agents. Feng Abstract, ¶¶ 27–28, 37, 43, 45, 49–50, 64–65; *see* Ans. 4–5.

FF4. Mason discloses an intradermal patch to deliver an active ingredient to a wound or ulcer having a permeable backing coated with a PVP-based hydrogel and containing one or more active ingredients. Mason Abstract, ¶¶ 10, 22, 34. The patch may further comprise permeation enhancers, ethyl cellulose, and silicone dioxide. *See, e.g., id.* ¶¶ 116, 119–122, 134, 135, 153.

FF5. Lipp discloses a transdermal therapeutic system including an adhesive matrix comprising, an active ingredient, a crystallization inhibitor and,

optionally, a penetration enhancer. Lipp Abstract. Lipp teaches ethyl cellulose, silicone dioxide, and PVP as known crystallization inhibitors. *Id.* at 2:1–18.

Analysis

The Examiner finds that it would have been obvious to treat chronic wounds such as diabetic foot ulcers with a

> transdermal formulation comprising [deferoxamine] as taught by [Gurtner with a] gel taught by Roreger comprising PVP, ethyl cellulose and nonionic emulsifier as a carrier for [deferoxamine]. One would have been motivated to do so because Roreger teaches that PVP combined with ethyl cellulose provide coherent flexible gel sheet like that delivers active agent in both rapid release manner and delaye[d] release manner, and nonionic emulsifier stabilizes the polymer.

Ans. 10–11. The Examiner similarly finds that it would have been obvious to treat skin ulcers and other chronic wounds using a patch comprising deferoxamine in a

> polymer carrier comprising combination of PVP, ethyl cellulose and nonionic emulsifier as taught by [Gurtner] combined with Roreger, and Feng. . . . One having ordinary skill in the art would have been motivated to deliver [deferoxamine] in the transdermal patch taught by Mason comprising backing layer and adhesive because Mason teaches such a patch is stable and secure to the skin. One would have been motivated to add permeation enhancer and crystallization inhibitor to the patch to improve the delivery of the [deferoxamine] and any other active agent in the patch and meanwhile maintain them un-crystallized.

Id. at 12.

Appellants respond that "[w]hile hydrophobic drugs can readily pass through the skin and tend to aggregate in the local adipose tissue,

hydrophilic drugs such as deferoxamine, do not readily pass through the skin, and tend to systemically distribute via the vasculature." App. Br. 4 (emphasis removed). In the present case, Appellants argue, the rejection is in error because the appealed claims include a non-ionic surfactant that enables transdermal delivery of deferoxamine by creating a reverse-micellar conformation and inhibiting crystallization. *Id.* at 4–5. According to Appellants, "[t]he reverse micelle technology achieved by the present formulation allows the local, transdermal delivery of this hydrophilic drug." *Id.* at 4.

Appellants further argue that "[a]lthough use of [deferoxamine] was desirable, it is not straightforward or obvious how to specifically enable transdermal penetration at a therapeutically useful level. A significant block to formulation has been crystallization of the active agent." *Id.* at 5. For example, "when 5% DMSO was included in the formulation, as is normally done to increase transdermal delivery, it was found to inhibit [deferoxamine] delivery." *Id.* Appellants present figures purporting to represent experimental data demonstrating the unexpected results achieved with the claimed formulation. *See id.* at 6–7.

As noted by the Examiner, however, Lipp teaches ethyl cellulose and PVP as known crystallization inhibitors, whereas the reverse-micelle configuration is not a limitation of the claims on appeal. *See* Ans. 5, 8. Moreover, nowhere do we discern any discussion of reverse micelles in the Specification, nor evidence that the permeation enhancer DMSO should be excluded from the formulation—to the contrary, both the Specification and the appealed claims appear to encompass the use of DMSO. *See* Spec. ¶ 58 ("the formulation comprises permeation enhancer, *e.g.* . . . dimethylsulfoxide

(DMSO). . . at a weight/weight concentration of from about 0.1 % to about 10%"); claim 19 ("wherein the biodegradable polymer film further comprises a permeation enhancer").

Further, with respect to the purported evidence of unexpected results, Appellants have not provided sufficient evidence by way of declaration or other means to support this position. Nor have Appellants indicated where this evidence is found in the Specification, or included a citation to a published article. Accordingly, we agree with the Examiner that Appellants' arguments regarding the exclusion of DMSO are based on opinion evidence, which is entitled to little or no weight. *See* Ans. 4. Mere lawyer's arguments and conclusory statements, which are unsupported by factual evidence, are entitled to little probative value. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). Attorney argument is not evidence. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). Nor can it take the place of evidence lacking in the record. *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977).

Based on the record before us, we agree with the Examiner that, "[e]ach [of the] elements of the instantly claimed method, steps or ingredients, are taught by combination of the cited references, and any reverse micelle formation or prevention of crystallization or enhancement of penetration is expected from the prior art method and dressing." Ans. 6. We conclude that the Examiner has established a prima facie case of obviousness, which, on the existing record, Appellants have not rebutted.

SUMMARY

We *affirm* the rejection of claims 1, 7–10, 16, 18–20, 22, 23, and 26–29 under pre-AIA 35 U.S.C. § 103(a) as unpatentable over the combination of Gurtner, Roreger, Feng, Mason, and Lipp.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a) (1)(iv).

AFFIRMED